510 (k) Summary

As Required by 21 section 807.92 (c)

K111133

JUN 24 2011

1. **Submitter Name:** SSC Surat Thani
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3. **Phone:** (+66) 77 277888
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5. **Contract Person:** Mrs. Sureerat Choosri (Quality manager)
6. **Date summary prepared:** 1 Feb , 2011
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 13900 49th Street North Clearwater, USA , FL 33762
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E. Harris
12. **Device Trade or Proprietary Name:** Non-sterile, powder-free latex examination gloves with protein claim (50 micrograms or less).
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Glove , Patient Examination , Latex
15. **Description of the Device:**

Non-Sterile, powder-free latex examination gloves with protein claim (50 micrograms or less).

16. **Indications for use of the device:** Based on 21 CFR Part 880.6250: "Patient examination glove." A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
17. **Summary of The Technological Characteristics of The devices :(According Guidance for Industry and FDA Staff - Medical Glove Guidance Manual(January 22, 2008))**

Non-Sterile, powder-free latex examination gloves with protein claim (50 micrograms or less) are summarized with the following technological characteristics:

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions: overall length; width, palm and finger thickness	ASTM D 3578-2005 (reapproved 2010)	Meets
Tensile strength: before and after aging	ASTM D 3578-2005 (reapproved 2010)	Meets
Ultimate elongation: before and after aging	ASTM D 3578-2005 (reapproved 2010)	Meets
Freedom from holes: pinholes AQL 2.5	ASTM D 3578-2005 (reapproved 2010)	Meets
Powder Free Residue	ASTM D 3578-2005 (reapproved 2010)	Meets
Protein Level	ASTM D 3578-2005 (reapproved 2010)	Meets

Biocompatability	Primary Skin Irritation in Rabbits	Passes
	Guinea Pig Sensitization	Passes

18. Substantial Equivalents Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

19. Conclusion

It can be concluded that Non-Sterile, powder-free latex examination gloves with protein claim (50 micrograms or less) will perform according to the glove performance standards referenced in section 17 above and meet ASTM standards, and FDA requirements. Consequently, this device is substantially equivalent to currently marketed devices.This device is safe and effective as the predicate device *Siam Sempermed Latex Patient Examination Glove , Powder free with protein claim (50 micrograms or less).* Indeed , it is equivalent.This is better expressed in the tabulated comparison as below.

Technical comparison of specific elements is attached in the main submission.

FDA file reference number	510k number : K100907
Attachments inside notification submission file	REFER TO APPENDIX 1
TECHNOLOGICAL CHARACTERISTICS	*Comparison result*
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Not applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (Not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (Not applicable)
Thermal safety	Identical (Not applicable)
Radiation safety	Identical (Not applicable)

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SSC Surat Thani

DECLARATION OF CONFORMITY

This is to declare and to confirm that **SSC Surat Thani** conforms in its manufacturing of Non- Sterile, powder-free latex examination gloves with protein claim (50 micrograms or less) to the following recognized standards, latest released revisions.

Standards met and standards tested against	Inapplicable requirements or deviations	Identification of any way(s) in which the standard was adapted for the application of the device, i.e., identification of an alternative series of tests that were performed	Specification of any deviations from each applicable standard	Specification of the differences that may exist between the tested device and the device to be marketed and justification of the test results	Name and address of any test laboratory or certification body involved in determining the conformance of the device with the standard and reference to any accreditaiton of those organization
Gloves: ASTM D 3578-05 (Reapproved 2010)					
Dimensions: overall length, width, palm and finger thickness:ASTM D3578-05(Reapproved 2010) (tested according to ASTM D3767-03(reapproved 2008)	Not applicable				Siam Sempermed Laboratories in Thailand
Tensile strength & Ultimate elongation: before and after aging: ASTM D3578-05 (Reapproved 2010) (tested according to ASTM D 412-2006ae 2 and ASTM D 573-04 (Reapproved 2010)	Not applicable				Siam Sempermed Laboratories in Thailand
Donning support: ASTM D 3578-05 (Reapproved 2010) : Powder Free residue: Tested according to ASTM D6124-06	Not applicable				Siam Sempermed Laboratories in Thailand
Water soluble Proteins: ASTM D 3578-05 (Reapproved 2010) Tested according to ASTM D5712-2010	Not applicable				Siam Sempermed Laboratories in Thailand
Freedom from holes: ASTM D 3578-05 (Reapproved 2010) Test according to ASTM D5151-06 Sampling inspection: ISO 2859-1:1999/Cor 1:2001	Not applicable				Siam Sempermed Laboratories in Thailand
Packages storage: ISO 2230-2002	Not applicable				
Supervision of product and design: QSR, MDD directives 93/42 Biocompatibility: ISO 10993-10/2002	Not applicable				- Consumer Product Testing ,70 New Dutch Lane , Fairfield, New Jersey , 07004-2514 Tel : 973 808 7111 Fax :973 808 7234

Name, Signature and Position:

Surat Quality Manager Date: 1 FEB 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. William E. Harris
President & CEO
SSC Surat Thani
13900 49th Street North
Clearwater, Florida 33762

JUN 24 2011

Re: K111133
Trade/Device Name: Non-Sterile Powder-Free Latex Examination Gloves with Protein Claim (50 Micrograms or Less)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: June 9, 2011
Received: June 9, 2011

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.\

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Non-Sterile, Powder-Free Latex Examination Glove with Protein Claim (50 micrograms or less).

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Elaine S. Marshall for Elizabeth Claverie Williams
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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